K100243

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Quintex Cervical Plating System

January 26, 2010

SEP - 2 2010

COMPANY: Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)

TRADE NAME: Quintex Cervical Plating System

COMMON NAME: Anterior Cervical Screw Spinal Fixation System

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis (87KWQ)

REGULATION NUMBER: 888.3060

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems (AIS), Inc., believes that the Quintex Cervical Plating System is substantially equivalent to the AIS ABC Cervical Plating Systems (K050813/K040017 /K000486/K974706), AIS Caspar Plate & Screw System (K953720/K936269/K913730) and the AIS Spectrum Cervical Spinal System (K022997/K050804).

DEVICE DESCRIPTION

The Aesculap Implant Systems (AIS) Quintex Cervical Plating System consists of dynamic and semi-constrained plate, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The AIS 3G Cervical Plating System is manufactured from Titanium/ Titanium Alloy and will be provided non-sterile.

INDICATIONS FOR USE

The Quintex Cervical Plating System is intended for the treatment of cervical spinal instability resulting from:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e. fracture or dislocation),
- Spinal Stenosis,
- Deformity (i.e., scoliosis, kyphosis, and/or lordosis),

- Tumors and instability associated with major reconstructive surgery related to tumor excision,
- Pseudoarthrosis as a result of failed spine surgery,
- Failed previous fusions,
- Symptomatic cervical spondylosis,
- Instability following surgery for the above indications.

Levels of anterior cervical intervertebral body screw fixation for this indication are from C_2-T_1.

Warning: This device is not approved or intended for screw attachment of fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The AIS Quintex Cervical Plating System is considered substantially equivalent to other legally marketed predicate systems. Biomechanical testing of the subject device was found to be similar in performance to previously cleared spinal systems with similar indications.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where relevant. Testing results demonstrate the AIS Quintex Cervical Plating System is safe and effective comparable to other predicate systems currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

SEP - 2 2010

Aesculap Implant Systems, LLC
% Ms. Lisa M. Boyle
Sr. Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K100243
Trade/Device Name: Quintex Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 30, 2010
Received: August 31, 2010

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bruehmer for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

SEP - 2 2010

510(k) Number: K100243

Device Name: Quintex Cervical Plating System

Indications for Use:

The Quintex Cervical Plating System is intended for the immobilization and stabilization of the spine as an adjunct to fusion in patients with:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e. fracture or dislocation),
- Spinal Stenosis,
- Deformity (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumors,
- Pseudoarthrosis as a result of failed spine surgery,
- Failed previous fusions,
- Symptomatic cervical spondylosis
- Instability following surgery for the above indications.

Levels of anterior cervical intervertebral body screw fixation for this indication are from C_2-T_1.

Warning: This device is not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100243